K021196

SECTION 9: 510 (k) SUMMARY (FFD&C ACT 513(I)(3)(A))

neuron Therapeutics, Inc.

Summary of Safety and Effectiveness Data
NEURON THERAPEUTICS INC., 14-GAUGE LUMBAR PUNCTURE SET
12 April 2002

Neuron Therapeutics, Inc.
81 Great Valley Parkway
Malvern, PA 19355

Contact Person

Judy P. Ways, Ph.D.
Vice President, Regulatory Affairs and Quality Assurance
Phone: (610) 578-9494 x112
Fax: (610) 578-9205

Name of Device

Proprietary Name:	Neuron Therapeutics, Inc., 14-Gauge Lumbar Puncture Set
Trade Name:	14-Gauge Lumbar Puncture Set
Common Name:	Sterile, 14-Gauge Lumbar Puncture Set
Classification Name:	Central Nervous System Fluid Shunt and Components
Regulatory Class:	II (21CFR § 882.5550)
Product Code:	84 JXG

Establishment Registration Number: 9001269

Device Classification

This device has been placed in a Class II for Central Nervous System shunt and components per 21 CFR § 882.5550.

Statement of Substantial Equivalence

The 14-Gauge Lumbar Catheter is the component of the14-Gauge Lumbar Puncture Set subject to 510(k) approval. Neuron Therapeutic Inc.'s (NTI) 14-Gauge Lumbar Catheter is substantially equivalent to the CODMAN Lumbar External Drainage Catheter with Touhy Needle that is currently marketed in the United States under 510(k) No. K964923. NTI's 14-Gauge Lumbar Catheter and 14-Gauge Lumbar Puncture Set have the same intended use, design characteristics, and similar methods of manufacture as the CODMAN Lumbar External Drainage Catheter with Touhy Needle.

Indications for Use

The Neuron Therapeutics Inc., 14-Gauge Lumbar Puncture Set has an substantially equivalent indication for use as the Codman Lumbar Drainage Catheter Kit. Both are indicated for temporary access to the lumbar subarachnoid region to drain cerebrospinal fluid (CSF) and other fluids of similar physical characteristics.

Physical Description

The Neuron Therapeutics 14-Gauge Lumbar Puncture Set, part number PN1000735, consists of a 14-Gauge Lumbar Catheter Kit, a Transparent Tegaderm™ Dressing, a Suture-less Catheter Anchor, and a Sterile Drape. These individual, sterile packaged components are provided in sealed tamper-evident packaging for single-use.

The 14-Gauge Lumbar Catheter Kit, part number PN1000737, contains a single 30 cm coiled lumbar catheter with an inner diameter of 1.25 mm, an outer diameter of 1.74 mm and 35 fenestrations. The shorter length, larger diameter and higher number of fenestrations of the catheter allow for decreased flow resistance and higher liquid flow rates. The higher number of fenestrations decreases the possibility of occlusion of the catheter during use. The catheter is constructed of polyurethane to provide resistance to kinking or collapsing. The catheter has13 location markings positioned at 1 cm intervals to assist the physician in identifying the location of the distal end of the catheter in the subarachnoid space. Special

markings are provided to indicate the location of the catheter tip, the proximal fenestration and the coiled shaft as they exit from the needle tip.

The 14-Gauge Lumbar Catheter Kit also contains a 15.0 cm, 14-gauge Extra-Thin Wall Touhy Needle and a 45 cm stainless steel flexible J-tip guidewire for inserting and guiding the catheter into the lumbar subarachnoid space. A 6-French Touhy-Borst Connector is also included for connection to equipment for patient monitoring or fluid collection.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD. 20850

JUL 1 2002

Neuron Therapeutics, Inc.
Judy P. Ways, Ph.D.
Vice President, Regulatory Affairs and Quality Assurance
81 Great Valley Parkway
Malvern, Pennsylvania 19355

Re: K021196
Trade Name: Neuron Therapeutics, Inc., 14-Gauge Lumbar Puncture Set
Regulation Number: 882.5550
Regulation Name: Central nervous system fluid shunt and components
Regulatory Class: II
Product Code: JXG
Dated: April 12, 2002
Received: April 16, 2002

Dear Dr. Ways:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

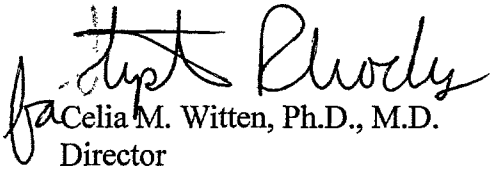
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

SECTION 7: STATEMENT OF INDICATIONS FOR USE

Device Name: Neuron Therapeutics, Inc., 14-Gauge Lumbar Puncture Set

Indications for Use: The Neuron Therapeutics Inc., 14-Gauge Lumbar Puncture Set is indicated for temporary access to the lumbar subarachnoid region to drain cerebrospinal fluid (CSF) and other fluids of similar physical characteristics.

510(k) Number (if known): K021196

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)
CONCURRENCE OF CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-the-Counter Use _____
(Per 21 CFR § 801.109)

(Optional Format 1-2-96)

(Division Sign-Off)
Division of General, Restorative and Neurological Devices

510(k) Number K021196